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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,057	10/17/2003	Eileen Tozer	1280-38	9210

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DIVERSA CORPORATION  
4955 DIRECTORS PLACE  
SAN DIEGO, CA 92121

EXAMINER

VENCI, DAVID J

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/688,057

Applicant(s)

TOZER ET AL.

Examiner

David J. Venci

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on July 28, 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 13, 18 and 36-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-17 and 19-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group 1, claims 1-35, and species A1, B3, C3, in the reply filed on July 28, 2005, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 13, 18 and 36-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected Groups or species, there being no allowable generic or linking claim.

Currently, claims 1-12, 14-17 and 19-35 are under examination.

### ***Priority***

Priority to 10/626,477 is not set forth in Applicants' declaration. Priority to 10/626,477 is required for obtaining priority to 60/399,272. Appropriate correction to the declaration is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Throughout claims 1-35, the recitation of hyphens between nouns (e.g. "protein-ligand") is indefinite because the structural and/or functional implications of said hyphens upon the scope of claims 1—3 5 are not clear.

In claim 30, step f), the recitation of "to form an Fab-antigen-anti digoxigenin IgG-anti IgG antibody-labeled anti digoxigenin antibody complex" is indefinite because it is not clear whether such a complex is formed. It is not clear whether such a complex is formed when "anti digoxigenin antibody comprising a detectable label" (step f) will cause steady state dissociation of "anti-digoxigenin IgG" from "Fab-antigen complex" (step d). It is not clear whether the formation of said "Fab-antigen-anti digoxigenin IgG-anti IgG antibody-labeled anti digoxigenin antibody complex" is conditional to omitted method steps not disclosed to the Office. Claim 12 is rejected for similar reasons.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11, 14-17, 19 and 22-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ladner et al. (US 5,223,409) in view of Maggio, ENZYME-IMMUNOASSAY, CRC Press (1980).

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Ladner et al. describe a method for screening (see col. 11, line 11, "screen colonies") for a ligand binding protein (see col. 11, line 12, "IPBD") comprising the steps: encapsulating (see col. 54, line 46, "infection") a cell (see col. 53, lines 63, "Phages") suspected of expressing a ligand binding protein (see col. 54, lines 12-13, "display of the OSP-IPBD protein on the phage surface") in a capsule comprising permeable walls (see col. 54, line 35, "bacterial host"), said walls containing a first capture agent (see col. 72, line 35, "Bacterial OSPs") for said ligand binding protein of interest (see col. 72, lines 41-42, "for fusion of the osp fragment to the ipbd fragment"), wherein the capture reagent does not prevent said ligand binding protein from interacting with its antigen (see col. 70, lines 47-48, "the OSP not constrain the orientation of the PBD domain"); incubating under conditions that allow expression of said ligand binding protein (see col. 54, line 46, "infection"); contacting with a ligand (see col. 30, line 32, "intervening molecules"; col. 85, line 52, "Target Materials");

Ladner et al. do not describe the detection scheme set forth in steps d) through g) of claim 1.

However, Maggio describes the scheming set forth in steps d) through g) of claim 1 (see p. 63, Table 3, "Bridge or unlabeled antibody"). Therefore, it would have been obvious for a person of ordinary skill in the art to modify the method for screening for a ligand binding protein, as described by Ladner et al., with the detection scheme set forth in steps d) through g) of claim 1 because Maggio teaches that such a scheme has the advantage of quantifying haptens (see p. 63, Table 3, "Advantages") and can be easily correlated to the amount of antigen initially present in a sample (see p. 221, fourth full paragraph)

With respect to claims 2-3, Ladner et al. describe flow cytometry (see col. 83, line 65).

With respect to claim 6, Ladner et al. describe beads (see col. 89, line 4).

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With respect to claim 23, Ladner et al. describe a method comprising isolating cells (see col. 98, line 22, "Recovery of Packages"), placing cells from different capsules in different locations on a first permeable solid substrate (see col. 94, lines 58-60, "plated on suitable medium"), re-infecting, re-detecting, and re-identifying (see col. 48, lines 15-16, "Second and Later Rounds of Variegation").

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Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ladner et al. (US 5,223,409) and Maggio, ENZYME-IMMUNOASSAY, CRC Press (1980), as applied to claims 1 and 9, and further in view of Adam et al., 15 J. PHARM. BIOMED. ANAL. 13 (1996).

Ladner et al. and Maggio describe a method for screening for a ligand binding protein as substantially described supra. Ladner et al. and Maggio do not describe digoxigenin epitopes.

However, Adam et al. describe digoxigenin epitopes for labeling haptenic drugs (see Title). Therefore, it would have been obvious for a person of ordinary skill in the art to modify the method for screening for a ligand binding protein, as described by Ladner et al. and Maggio, with digoxigenin epitopes because Adam et al. discovered that digoxigenin "appears to be a more specific indicator for mammalian biological samples" (see p. 14, col. 1, lines 15-21).

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**Conclusion**


No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci  
Examiner  
Art Unit 1641

djv

  
LONG V. LE  
SUPERVISOR, PATENT EXAMINER  
TECHNOLOGY CENTER 1600

09/06/05